

104TH CONGRESS
2D SESSION

H. R. 3482

To protect the privacy of health information in the age of genetic and other new technologies, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 16, 1996

Mr. McDERMOTT (for himself, Mr. SERRANO, and Ms. PELOSI) introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committee on Government Reform and Oversight, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To protect the privacy of health information in the age of genetic and other new technologies, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Medical Privacy in the Age of New Technologies Act of
6 1996”.

7 (b) TABLE OF CONTENTS.—The table of contents for
8 this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Findings and purposes.
- Sec. 3. Definitions.

TITLE I—INDIVIDUALS' RIGHTS

Subtitle A—Review of Protected Health Information by Subjects of the Information

- Sec. 101. Inspection and copying of protected health information.
- Sec. 102. Correction or amendment of protected health information.
- Sec. 103. Notice of information practices.

Subtitle B—Establishment of Safeguards

- Sec. 111. Establishment of safeguards.
- Sec. 112. Accounting for disclosures.
- Sec. 113. Prohibition against retaliation.

TITLE II—RESTRICTIONS ON USE AND DISCLOSURE

- Sec. 201. General rules regarding use and disclosure.
- Sec. 202. Authorizations for disclosure of protected health information for treatment or payment.
- Sec. 203. Authorizations for disclosure of protected health information for purposes other than treatment or payment.
- Sec. 204. Creation of nonidentifiable and coded information.
- Sec. 205. Next of kin and directory information.
- Sec. 206. Emergency circumstances.
- Sec. 207. Oversight.
- Sec. 208. Accreditation.
- Sec. 209. Public health.
- Sec. 210. Health research.
- Sec. 211. Judicial and administrative purposes.
- Sec. 212. General requirements governing subpoenas.
- Sec. 213. Additional requirements for law enforcement access.

TITLE III—SANCTIONS

Subtitle A—Civil Sanctions

- Sec. 301. Civil penalty.
- Sec. 302. Civil action.

Subtitle B—Criminal Sanctions

- Sec. 311. Wrongful disclosure of protected health information.

TITLE IV—MISCELLANEOUS

- Sec. 401. Regulations.
- Sec. 402. Relationship to other laws.
- Sec. 403. Effective dates.
- Sec. 404. Applicability.

1 SEC. 2. FINDINGS AND PURPOSES.

- 2 (a) FINDINGS.**—The Congress finds as follows:

1 (1) Health information plays a vital role in
2 every aspect of an individual's life. It includes some
3 of the most sensitive information available about an
4 individual.

5 (2) An individual's health information is cur-
6 rently accessible to many people who do not need the
7 information to provide health care to the individual,
8 often without the individual's knowledge or consent.

9 (3) Individuals will be deterred from using the
10 health care system unless they are assured that the
11 confidentiality of their health information will be re-
12 spected.

13 (4) There exists little Federal protection of the
14 confidentiality of an individual's health information.

15 (5) While health information often is trans-
16 ferred across State lines, protection of the confiden-
17 tiality of health information varies greatly from
18 State to State, with little protection in some States.

19 (6) New technologies increase the importance of
20 addressing new threats to the confidentiality of
21 health information. For example, technologies that
22 permit an individual's health information to be com-
23 puterized increase the possibility of unauthorized
24 electronic access to the information. Technologies
25 that provide genetic information provide information

1 not just about an individual's current health but also
2 about the individual's potential future health and the
3 health of the individual's relatives. This creates po-
4 tential new uses and abuses of genetic health infor-
5 mation that need to be addressed by legislation.

6 (7) The potential benefits from new genetic
7 technologies will not be realized if individuals cannot
8 trust that their health information is safe from un-
9 authorized uses.

10 (b) PURPOSES.—The purposes of this Act are as fol-
11 lows:

12 (1) To recognize that there is a right to privacy
13 with respect to health information, including genetic
14 information, and that this right must be protected
15 accordingly.

16 (2) To ensure that an individual's interest in
17 the privacy of their health information cannot be
18 overridden without meaningful notice and informed
19 consent, except in limited circumstances where there
20 is a compelling public interest.

21 (3) To provide individuals—

22 (A) access to health information of which
23 they are the subject; and

1 (B) the power to challenge the accuracy
2 and completeness of, and amend or correct,
3 records containing such information.

4 (4) To establish a minimum Federal standard
5 for the protection of health information which will
6 promote confidentiality while allowing efficient
7 transfer of health information between States.

8 (5) To help ensure the confidentiality of com-
9 puterized or electronically transferred health infor-
10 mation.

11 (6) To restrict the gathering of aggregate
12 health information for financial gain or other pur-
13 poses without each subject's knowledge or consent.

14 (7) To establish strong and effective remedies
15 for violations of this Act.

16 **SEC. 3. DEFINITIONS.**

17 As used in this Act:

18 (1) ACCREDITING BODY.—The term “accredit-
19 ing body” means a body, committee, organization, or
20 institution that has been authorized by law, or is
21 recognized by a health care regulating authority,
22 with respect to accreditation, licensing, or
23 credentialing of health care providers or health care
24 facilities.

1 (2) CODED HEALTH INFORMATION.—The term
2 “coded health information” means any protected
3 health information—

4 (A) in which all identifying information
5 has been replaced by a unique identifier, and
6 where neither the remaining information nor
7 the unique identifier, on its face, identifies an
8 individual;

9 (B) which cannot easily be used or manip-
10 ulated in a manner that reveals the identity of
11 an individual; and

12 (C) which can only be linked or matched to
13 other information in a manner that reveals the
14 identity of an individual by a person authorized
15 to carry out such functions under section 204.

16 (3) DISCLOSE.—The term “disclose” when used
17 with respect to protected health information that is
18 held by a health information trustee, means to re-
19 lease, transfer, provide access to, or otherwise di-
20 vulge the information to any person other than an
21 individual who is the subject of the information.
22 Such term includes the placement of protected
23 health information into a computerized data base,
24 networked computer system, or any other electronic
25 or magnetic data system, that more than one person

1 may access by any means. Such term does not in-
2 clude oral communication between an individual who
3 is the subject of protected health information and a
4 health care provider delivering health care to such
5 individual.

6 (4) ELECTRONIC.—The term “electronic”, when
7 used with reference to information, means—

8 (A) in electronic or magnetic form;

9 (B) in an optical storage form;

10 (C) computer-based;

11 (D) computer-associated; or

12 (E) in some other form that—

13 (i) is appropriate for non-paper-based
14 information processing or storage; and

15 (ii) exists on the date of the enact-
16 ment of this Act or is developed subse-
17 quent to such date.

18 (5) HEALTH CARE.—The term “health care”
19 means—

20 (A) any sale or dispensing of a drug, de-
21 vice, equipment, or other item to an individual,
22 or for the use of an individual, pursuant to a
23 prescription; and

1 (B) any preventive, predictive, diagnostic,
2 therapeutic, rehabilitative, maintenance, or pal-
3 liative care, counseling, service, or procedure—

4 (i) with respect to the physical or
5 mental condition of an individual; or

6 (ii) affecting the structure or function
7 of the human body or any part of the
8 human body, including individual cells and
9 their components.

10 (6) HEALTH CARE PROVIDER.—The term
11 “health care provider” means a person who, with re-
12 spect to a specific item of protected health informa-
13 tion, receives, creates, uses, maintains, or discloses
14 the information while acting in whole or in part in
15 the capacity of—

16 (A) a person who is licensed, certified, reg-
17 istered, or otherwise authorized by law to pro-
18 vide an item or service that constitutes health
19 care, in the ordinary course of business or prac-
20 tice of a profession; or

21 (B) a Federal or State program that di-
22 rectly provides items or services that constitute
23 health care to beneficiaries.

24 (7) HEALTH INFORMATION TRUSTEE.—The
25 term “health information trustee” means—

1 (A) a person who is a health care provider,
2 health plan, health oversight agency, public
3 health authority, health researcher, employer,
4 insurer, school, institution of higher education,
5 or insurance support organization, insofar as
6 the person creates, receives, obtains, maintains,
7 uses, or transmits protected health information;
8 or

9 (B) any employee, agent, or contractor of
10 a person described in subparagraph (A), insofar
11 as the employee, agent, or contractor creates,
12 receives, obtains, maintains, uses, or transmits
13 protected health information.

14 (8) HEALTH OVERSIGHT AGENCY.—The term
15 “health oversight agency” means a person who—

16 (A) performs or oversees the performance
17 of an assessment, investigation, or prosecution
18 relating to—

19 (i) compliance with legal or fiscal
20 standards pertinent to health care fraud,
21 including fraudulent claims regarding
22 health care, health services or equipment,
23 or related activities and items; or

24 (ii) the protection of individuals from
25 harm, abuse, neglect, or exploitation; and

1 (B) is a public agency, acting on behalf of
2 a public agency, acting pursuant to a require-
3 ment of a public agency, or carrying out activi-
4 ties under a Federal or State law governing an
5 assessment, investigation, or prosecution de-
6 scribed in subparagraph (A).

7 (9) HEALTH PLAN.—The term “health plan”
8 means any health insurance plan, including any hos-
9 pital or medical service plan, dental or other health
10 service plan or health maintenance organization
11 plan, or other program providing payment for health
12 care, whether or not funded through the purchase of
13 insurance.

14 (10) HEALTH RESEARCHER.—The term “health
15 researcher” means a person who conducts, using
16 protected health information, a systematic investiga-
17 tion, or research development, testing, or evaluation,
18 to develop or contribute to scientific or medical
19 knowledge.

20 (11) INDIVIDUAL REPRESENTATIVE.—The term
21 “individual representative” means any individual le-
22 gally empowered to make decisions concerning the
23 provision of health care to an individual (where the
24 individual lacks the legal capacity under State law to

1 make such decisions) or the administrator or execu-
2 tor of the estate of a deceased individual.

3 (12) INSURANCE SUPPORT ORGANIZATION.—

4 (A) IN GENERAL.—Subject to subpara-
5 graph (B), the term “insurance support organi-
6 zation” means any person who regularly en-
7 gages, in whole or in part, in the practice of as-
8 sembling and providing information about indi-
9 viduals to an insurer or health plan for insur-
10 ance transactions, including—

11 (i) the furnishing of consumer reports
12 or investigative consumer reports to an in-
13 surer or health plan for use in connection
14 with an insurance transaction; or

15 (ii) the collection of personal informa-
16 tion from insurers, health plans, or other
17 insurance support organizations for the
18 purpose of detecting or preventing fraud or
19 material misrepresentation in connection
20 with insurance underwriting or insurance
21 claim activity.

22 (B) PERSONS EXCLUDED.—Such term
23 does not include any person who is treated as
24 a health information trustee under any other
25 provision of this Act.

1 (13) LAW ENFORCEMENT INQUIRY.—The term
2 “law enforcement inquiry” means an official law en-
3 forcement investigation or proceeding inquiring into
4 a violation of, or failure to comply with, any law.

5 (14) NONIDENTIFIABLE HEALTH INFORMA-
6 TION.—The term “nonidentifiable health informa-
7 tion” means information that would be protected
8 health information, except that—

9 (A) it is impossible to ascertain, based on
10 the information, or on any codes or identifiers
11 related to the information, the identity of any
12 individual whose health or condition is the sub-
13 ject of the information; and

14 (B) it cannot be linked or matched by a
15 foreseeable method to any other information
16 that pertains to any such individual.

17 (15) PERSON.—The term “person” means any
18 of the following:

19 (A) An individual.

20 (B) A government.

21 (C) A governmental subdivision, agency or
22 authority.

23 (D) A corporation.

24 (E) A company.

25 (F) An association.

- 1 (G) A firm.
- 2 (H) A partnership.
- 3 (I) A society.
- 4 (J) An estate.
- 5 (K) A trust.
- 6 (L) A joint venture.
- 7 (M) An individual representative.
- 8 (N) Any other legal entity.

9 (16) PROTECTED HEALTH INFORMATION.—The
10 term “protected health information” means any in-
11 formation, including information derived from a bio-
12 logical sample from the human body and demo-
13 graphic information about an individual, whether
14 oral or recorded in any form or medium, that—

15 (A) is created or received by a health infor-
16 mation trustee or an accrediting body;

17 (B) relates to—

18 (i) the past, present, or future phys-
19 ical or mental health, predisposition, or
20 condition of an individual, or individuals
21 related by blood to the individual;

22 (ii) the provision of health care to an
23 individual; or

1 (iii) the past, present, or future pay-
2 ment for the provision of health care to an
3 individual; and

4 (C)(i) identifies such individual;

5 (ii) with respect to which there is a reason-
6 able basis to believe that the information can be
7 used to identify such individual; or

8 (iii) could be linked or matched by a fore-
9 seeable method to any other information which
10 pertains to such individual.

11 (17) PROTECTED HEALTH INFORMATION
12 SUBFILE.—The term “protected health information
13 subfile” means any amount of protected health in-
14 formation which is segregated pursuant to section
15 201(c).

16 (18) PUBLIC HEALTH AUTHORITY.—The term
17 “public health authority” means an authority or in-
18 strumentality of the United States, a State, or a po-
19 litical subdivision of a State that—

20 (A) is charged by statute with responsibil-
21 ity for public health matters; and

22 (B) is engaged in such activities as injury
23 reporting, public health surveillance, and public
24 health investigation or intervention.

1 (19) SECRETARY.—The term “Secretary”
2 means the Secretary of Health and Human Services.

3 (20) STATE.—The term “State” includes the
4 District of Columbia, Puerto Rico, the Virgin Is-
5 lands, Guam, American Samoa, and the Northern
6 Mariana Islands.

7 (21) WRITING.—The term “writing” means
8 writing in either a paper-based or electronic form.

9 **TITLE I—INDIVIDUALS’ RIGHTS**
10 **Subtitle A—Review of Protected**
11 **Health Information by Subjects**
12 **of the Information**

13 **SEC. 101. INSPECTION AND COPYING OF PROTECTED**
14 **HEALTH INFORMATION.**

15 (a) IN GENERAL.—Except as provided in subsections
16 (b) and (h), a health information trustee shall permit an
17 individual who is the subject of protected health informa-
18 tion, or the individual’s designee, to inspect and copy pro-
19 tected health information concerning the individual, in-
20 cluding records created under section 102, that the trustee
21 maintains. A health information trustee may require an
22 individual to reimburse the trustee for the reasonable cost
23 of such inspection and copying.

24 (b) EXCEPTION.—

1 (1) IN GENERAL.—A health care provider who
2 is delivering, or has delivered, health care to an indi-
3 vidual who is the subject of protected health infor-
4 mation relating to such health care is not required
5 by this section to permit inspection or copying of the
6 information, where such inspection or copying rea-
7 sonably could be expected to endanger the life or
8 physical or mental safety of any individual.

9 (2) ALTERNATIVE DISCLOSURE.—In any case
10 where a health care provider determines that the
11 provider, pursuant to paragraph (1), will not permit
12 an individual to inspect or copy protected health in-
13 formation, the provider may permit inspection or
14 copying by the individual's designee.

15 (c) DENIAL OF A REQUEST FOR INSPECTION OR
16 COPYING.—If a health information trustee denies a re-
17 quest for inspection or copying under subsection (b), the
18 trustee shall inform the individual in writing of—

19 (1) the reasons for the denial of the request;

20 (2) any procedures for further review of the de-
21 nial; and

22 (3) the individual's right to file with the trust-
23 ee, if the individual so wishes, a concise statement
24 setting forth the request for inspection or copying.

1 (d) STATEMENT REGARDING REQUEST.—If an indi-
2 vidual has filed a statement under subsection (c)(3) set-
3 ting forth the request, the health information trustee in
4 any subsequent disclosure of the portion of the informa-
5 tion requested shall include—

- 6 (1) a copy of the individual’s statement; and
7 (2) a concise statement of the reasons for deny-
8 ing the request for inspection or copying.

9 (e) RULE OF CONSTRUCTION.—This section shall not
10 be construed to require a health information trustee to
11 conduct a formal, informal, or other hearing or proceeding
12 concerning a request for inspection or copying of protected
13 health information.

14 (f) INSPECTION AND COPYING OF SEGREGABLE POR-
15 TION.—A health information trustee shall permit inspec-
16 tion and copying under subsection (a) of any reasonably
17 segregable portion of a record after deletion of any portion
18 that is exempt under subsection (b).

19 (g) DEADLINE.—A health information trustee shall
20 comply with or deny, in accordance with subsection (c),
21 a request for inspection or copying of protected health in-
22 formation under this section within the 30-day period be-
23 ginning on the date on which the trustee receives the re-
24 quest.

1 (h) RULES GOVERNING AGENTS AND CONTRAC-
2 TORS.—

3 (1) IN GENERAL.—A person acting in the ca-
4 pacity of an agent or contractor of a health care
5 provider, health plan, health oversight agency, public
6 health authority, health researcher, employer, in-
7 surer, school, institution of higher education, or in-
8 surance support organization is not responsible for
9 providing for the inspection or copying of protected
10 health information under this section, except when
11 the agent or contractor has been notified by their
12 principal that a request for inspection or copying
13 has been made to the principal under section (a) and
14 has not been denied under section (b).

15 (2) CODED HEALTH INFORMATION.—In any
16 case where a person acting in the capacity of an
17 agent or contractor of a health care provider, health
18 plan, health oversight agency, public health author-
19 ity, health researcher, employer, insurer, school, in-
20 stitution of higher education, or insurance support
21 organization is requested to provide for the inspec-
22 tion or copying of coded health information under
23 this section, the person shall inform the individual
24 making the request that the individual should con-
25 tact a person authorized under section 204 to link

1 or match the coded health information to reveal the
2 identity of the individual who is the subject of the
3 information.

4 **SEC. 102. CORRECTION OR AMENDMENT OF PROTECTED**
5 **HEALTH INFORMATION.**

6 (a) IN GENERAL.—Unless proceeding under sub-
7 section (b), and except as provided in subsection (f), a
8 health information trustee, within the 45-day period be-
9 ginning on the date on which the trustee receives from
10 an individual a written request to correct or amend pro-
11 tected health information about the individual—

12 (1) shall make the correction or amendment re-
13 quested;

14 (2) shall inform the individual of the correction
15 or amendment that has been made; and

16 (3) shall make reasonable efforts to inform any
17 person who is identified by the individual, and to
18 whom the uncorrected or unamended portion of the
19 information was previously disclosed, of the correc-
20 tion or amendment that has been made.

21 (b) REFUSAL TO CORRECT OR AMEND.—If the
22 health information trustee refuses to make the correction
23 or amendment, the trustee shall inform the individual,
24 within the 45-day period beginning on the date on which
25 the trustee receives the individual's request, of—

1 (1) the reasons for the refusal to make the cor-
2 rection or amendment;

3 (2) any procedures for further review of the re-
4 fusal; and

5 (3) the individual's right to file with the trust-
6 ee, if the individual so wishes, a concise statement
7 setting forth the requested correction or amendment
8 and the individual's reasons for disagreeing with the
9 refusal.

10 (c) STATEMENT OF DISAGREEMENT.—If an individ-
11 ual has filed a statement of disagreement under subsection
12 (b)(3), the health information trustee in any subsequent
13 disclosure of the disputed portion of the information—

14 (1) shall include a copy of the individual's
15 statement; and

16 (2) shall include a concise statement of the rea-
17 sons for not making the requested correction or
18 amendment.

19 (d) RULE OF CONSTRUCTION.—This section shall not
20 be construed to require a health information trustee to
21 conduct a formal, informal, or other hearing or proceeding
22 concerning a request for a correction or amendment to
23 protected health information.

24 (e) CORRECTION.—For purposes of subsection (a), a
25 correction is deemed to have been made to protected

1 health information when information that has been dis-
 2 puted by an individual has been corrected, clearly marked
 3 as incorrect, or supplemented by correct information.

4 (f) RULES GOVERNING AGENTS AND CONTRAC-
 5 TORS.—A person acting in the capacity of an agent or con-
 6 tractor of a health care provider, health plan, health over-
 7 sight agency, public health authority, health researcher,
 8 employer, insurer, school, institution of higher education,
 9 or insurance support organization is not authorized to
 10 make corrections or amendments to protected health infor-
 11 mation received from their principal, except when the
 12 agent or contractor has been asked by the principal to ful-
 13 fill the principal's obligations under this section.

14 **SEC. 103. NOTICE OF INFORMATION PRACTICES.**

15 (a) PREPARATION OF WRITTEN NOTICE.—A health
 16 information trustee shall prepare and provide, in accord-
 17 ance with subsection (b), a written notice containing the
 18 following:

19 (1) INDIVIDUALS' RIGHTS.—A description of
 20 the following rights of an individual who is a subject
 21 of protected health information maintained by the
 22 trustee:

23 (A) The right of the individual to request
 24 segregation of protected health information, and
 25 to restrict the use of such information by em-

1 ployees, agents, and contractors of the trustee,
2 under section 201(c).

3 (B) The right of the individual to inspect,
4 copy, amend, and correct the protected health
5 information under sections 101 and 102.

6 (C) The right of the individual to object to
7 the disclosure of the information to next of kin
8 or in directory information under section 205.

9 (D) The circumstances under which the in-
10 information may be used or disclosed without an
11 authorization executed by the individual.

12 (E) The right of the individual not to have
13 employment or the receipt of services condi-
14 tioned upon the execution by the individual of
15 an authorization for disclosure or use for any
16 purpose other than treatment or payment.

17 (F) The procedures the individual must
18 follow in order to exercise the foregoing rights.

19 (2) TRUSTEE INFORMATION PRACTICES.—A de-
20 scription of the trustee's health information prac-
21 tices, including the safeguards and practices used to
22 protect such information.

23 (b) AVAILABILITY OF NOTICE TO SUBJECTS.—A
24 health information trustee shall provide a copy of a notice

1 prepared under this section to an individual who is a sub-
2 ject of protected health information—

3 (1) along with any request for authorization to
4 use or disclose the information created pursuant to
5 section 202 or 203 and presented by the trustee to
6 the individual for execution;

7 (2) at the first practicable opportunity after the
8 trustee uses or discloses the information without an
9 authorization executed by the individual;

10 (3) at the first practicable opportunity after a
11 health information trustee commences the collection
12 of the information; or

13 (4) when the individual requests to inspect,
14 copy, correct, or amend their protected health infor-
15 mation pursuant to section 101 or 102.

16 **Subtitle B—Establishment of** 17 **Safeguards**

18 **SEC. 111. ESTABLISHMENT OF SAFEGUARDS.**

19 (a) IN GENERAL.—A health information trustee shall
20 establish and maintain appropriate administrative, tech-
21 nical, and physical safeguards to ensure the confidential-
22 ity, security, accuracy, and integrity of protected health
23 information created, received, obtained, maintained, used
24 or transmitted by the trustee.

25 (b) SAFEGUARDS FOR ELECTRONIC INFORMATION.—

1 (1) APPLICATION AND CONSTRUCTION.—

2 (A) APPLICATION.—This subsection ap-
3 plies only with respect to protected health infor-
4 mation that is electronic.

5 (B) CONSTRUCTION.—Nothing in this Act
6 shall be construed to require that protected
7 health information be created, received, main-
8 tained, used, or disclosed in electronic form.

9 (2) REQUIREMENTS FOR ELECTRONIC MAINTENANCE,
10 NANCE, USE, AND DISCLOSURE.—The Secretary
11 shall develop, and by regulation impose on health in-
12 formation trustees, requirements for the electronic
13 maintenance, use, and disclosure of protected health
14 information. Such requirements shall include the fol-
15 lowing:

16 (A) CONTROL OF ACCESS TO PROTECTED
17 HEALTH INFORMATION.—

18 (i) IN GENERAL.—A health informa-
19 tion trustee shall implement controls with
20 respect to access to electronic protected
21 health information. The trustee may grant
22 a request by any person for access to such
23 information for use by the health informa-
24 tion trustee, or for disclosure to another

1 health information trustee, only after veri-
2 fying that—

3 (I) the person making the re-
4 quest can prove their identity; and

5 (II) the proposed use of the pro-
6 tected health information, or the re-
7 quested disclosure, is authorized
8 under this Act.

9 (ii) AUTHENTICATION OF IDENTITY
10 OF REQUESTERS.—A health information
11 trustee shall use a method of verification
12 to verify the identity of persons requesting
13 access to electronic protected health infor-
14 mation. A health information trustee who
15 issues a device that verifies the identity of
16 a person making a request for information
17 for purposes of this clause shall instruct
18 the person in the proper care and use of
19 the device and shall require the person to
20 protect the device from misuse. Any system
21 used by a health information trustee to
22 maintain verification information collected
23 under this clause shall prevent the disclo-
24 sure of such verification information to any
25 person other than a person who is specifi-

1 cally authorized to receive such informa-
2 tion.

3 (B) ACCESS FOR USE BY HEALTH INFOR-
4 MATION TRUSTEE.—A health information trust-
5 ee shall limit the persons who may use pro-
6 tected health information created or maintained
7 by the trustee in electronic form to persons spe-
8 cifically authorized by the trustee to use such
9 information consistent with this Act.

10 (C) DISCLOSURE TO OTHERS.—

11 (i) PROTECTION OF REQUESTS FOR
12 DISCLOSURE AND RESPONSES.—A health
13 information trustee who requests, using
14 electronic means, to receive protected
15 health information, or who responds, using
16 electronic means, to such a request, shall
17 implement procedures to prevent the inter-
18 ception of such request or response by per-
19 sons who are not authorized to intercept it.

20 (ii) IDENTIFICATION OF SUBJECT.—A
21 health information trustee who receives,
22 using electronic means, a request for pro-
23 tected health information from another
24 health information trustee may not provide
25 such information in response to the request

1 unless the request contains sufficient de-
2 tails to uniquely identify one individual
3 who is the subject of the request.

4 (D) AUDIT TRAIL.—

5 (i) ACCESS TO INFORMATION MAIN-
6 TAINED BY OTHERS.—A health informa-
7 tion trustee shall maintain an electronic
8 record concerning each attempt that is
9 made by the trustee, whether authorized or
10 unauthorized, successful or unsuccessful,
11 to access protected health information that
12 is maintained by any other health informa-
13 tion trustee in electronic form. The record
14 shall include the identity of the specific in-
15 dividual attempting to gain such access
16 and information sufficient to identify the
17 information sought.

18 (ii) ACCESS TO INFORMATION MAIN-
19 TAINED BY THE TRUSTEE.—A health in-
20 formation trustee shall maintain an elec-
21 tronic record concerning each attempt that
22 is made by the trustee, or by any other
23 person, whether authorized or unauthor-
24 ized, successful or unsuccessful, to access
25 protected health information maintained by

1 the trustee in electronic form. The record
2 shall include the identity of the specific in-
3 dividual attempting to gain such access
4 and information sufficient to identify the
5 information sought.

6 (3) REVIEW OF REQUIREMENTS.—The Sec-
7 retary from time to time shall review the require-
8 ments developed and imposed under paragraph (2),
9 to determine whether technological advances or other
10 factors make necessary changes to the requirements.
11 If the Secretary determines that such changes are
12 necessary, the Secretary shall make them.

13 **SEC. 112. ACCOUNTING FOR DISCLOSURES.**

14 (a) IN GENERAL.—

15 (1) PERSONS NOT ACTING AS AGENTS OR CON-
16 TRACTORS.—Except as provided in paragraph (2), a
17 health information trustee shall create and maintain,
18 with respect to any protected health information dis-
19 closure made by the trustee that is not related to
20 treatment, a record of the disclosure in accordance
21 with regulations promulgated by the Secretary.

22 (2) AGENTS AND CONTRACTORS.—A person
23 acting in the capacity of an agent or contractor of
24 a health care provider, health plan, health oversight
25 agency, public health authority, health researcher,

1 employer, insurer, school, institution of higher edu-
2 cation, or insurance support organization shall cre-
3 ate and maintain, with respect to any protected
4 health information disclosure made by the person
5 that is authorized under one of section 202, 203,
6 204, or 206 through 213, a record of the disclosure
7 in accordance with regulations promulgated by the
8 Secretary.

9 (b) RECORD OF DISCLOSURE PART OF PROTECTED
10 HEALTH INFORMATION.—A record created and main-
11 tained under subsection (a) shall be maintained as pro-
12 tected health information for not less than 7 years.

13 **SEC. 113. PROHIBITION AGAINST RETALIATION.**

14 A health information trustee may not adversely affect
15 another person, directly or indirectly, because such person
16 has exercised a right under this Act, disclosed information
17 relating to a possible violation of this Act, or associated
18 with, or assisted a person in the exercise of a right under
19 this Act.

TITLE II—RESTRICTIONS ON USE AND DISCLOSURE

SEC. 201. GENERAL RULES REGARDING USE AND DISCLOSURE.

(a) GENERAL RULE.—A health information trustee may not use or disclose protected health information except as authorized under this title.

(b) SCOPE OF USE AND DISCLOSURE.—

(1) COMPATIBILITY WITH PURPOSE FOR OBTAINING INFORMATION.—A health information trustee may not use, or disclose to any person, protected health information unless the use or disclosure is compatible with and directly related to—

(A) the purposes for which the information was obtained by the health information trustee; and

(B) in the case where an individual has executed an authorization, for the specific purpose authorized by the individual.

(2) LIMITATION ON AMOUNT OF INFORMATION.—

(A) USE AND DISCLOSURE.—

(i) IN GENERAL.—Every use and disclosure of protected health information by a health information trustee shall be lim-

1 ited to the minimum amount of informa-
2 tion necessary to accomplish the purpose
3 for which the information is used or dis-
4 closed.

5 (ii) NONIDENTIFIABLE INFORMA-
6 TION.—A health information trustee shall
7 use and disclose nonidentifiable health in-
8 formation, in lieu of protected health infor-
9 mation, to maximum extent possible, con-
10 sistent with the purpose for the use or dis-
11 closure.

12 (iii) CODED HEALTH INFORMATION.—
13 A health information trustee shall use and
14 disclose coded health information, in lieu of
15 any other kind of protected health informa-
16 tion, to maximum extent possible, consist-
17 ent with the purpose for the use or disclo-
18 sure.

19 (B) COLLECTION, CREATION, AND RE-
20 QUESTS.—A health information trustee may not
21 collect, create, or request the disclosure of,
22 more protected health information than is nec-
23 essary to accomplish the purpose for which the
24 information is collected, created, or requested.

1 (c) SPECIAL RULES FOR PROTECTED HEALTH IN-
2 FORMATION SUBFILES.—

3 (1) SEGREGATION.—A health information trust-
4 ee shall, upon creating or obtaining protected health
5 information, comply with the request of a subject of
6 such information—

7 (A) to segregate any amount or type of
8 protected health information; and

9 (B) to maintain such protected health in-
10 formation as one or more protected health in-
11 formation subfiles.

12 (2) DISCLOSURE AND USE.—

13 (A) IN GENERAL.—Subject to subpara-
14 graph (B), a person, other than a health care
15 provider who is otherwise authorized to access
16 or use protected health information about an
17 individual contained in a protected health infor-
18 mation subfile for purposes of delivering health
19 care to the individual, may not use or disclose
20 any information that is in the subfile, except as
21 authorized under section 202, 203, or 206.

22 (B) EMPLOYEES, AGENTS, CONTRAC-
23 TORS.—A health information trustee, with re-
24 spect to a protected health information subfile
25 created pursuant to paragraph (1), shall limit

1 use of the subfile to those employees, contrac-
2 tors, or agents of the trustee, described by
3 name or job title, who, with respect to the
4 subfile are authorized, pursuant to section 202
5 or 203, to use or obtain such information.

6 (C) INFORMATION ON EXISTENCE OF
7 SUBFILES.—A health information trustee may
8 not disclose information about the existence of
9 a health information subfile to any person who
10 is not authorized to obtain, access, or use the
11 subfile.

12 (d) NO GENERAL REQUIREMENT TO DISCLOSE.—

13 Nothing in this title that permits a disclosure of protected
14 health information shall be construed to require such dis-
15 closure.

16 (e) LIMITATIONS ON DISCLOSURE AND USE WITHIN
17 A TRUSTEE.—

18 (1) CONDITION OF TREATMENT OR PAYMENT.—

19 A health information trustee may not condition de-
20 livery of health care, or payment for services, on the
21 receipt of an authorization described in section 202
22 or 203 that authorizes the disclosure of protected
23 health information to any employee, agent, or con-
24 tractor who does not perform a legitimate and nec-

1 essary function with respect to the purpose for
2 which the information was obtained or created.

3 (2) EMPLOYMENT.—A health information trust-
4 ee may not condition employment on the receipt of
5 an authorization described in section 202 or 203
6 that authorizes the disclosure of protected health in-
7 formation to any employee, agent, or contractor who
8 does not perform a legitimate and necessary function
9 with respect to the purpose for which the informa-
10 tion was obtained or created.

11 (f) IDENTIFICATION OF DISCLOSED INFORMATION AS
12 PROTECTED INFORMATION.—Except as provided in this
13 title, a health information trustee may not disclose pro-
14 tected health information unless such information is clear-
15 ly identified as protected health information that is subject
16 to this title.

17 (g) INFORMATION IDENTIFYING PROVIDERS.—The
18 Secretary shall issue regulations protecting information
19 identifying health care providers in order to promote the
20 availability of health care services.

21 (h) USE OF SOCIAL SECURITY NUMBER.—A Social
22 Security account number, or a derivative of a Social Secu-
23 rity account number, may not be used by a health informa-
24 tion trustee for any purpose relating to protected health
25 information or the use or disclosure of such information.

1 (i) MULTIPLE RECORDS.—No person may aggregate,
2 compile, link, or match protected health information held
3 by two or more different health information trustees, or
4 two or more protected health information subfiles pertain-
5 ing to an individual, without obtaining specific authoriza-
6 tion under section 202 or 203 for such use.

7 (j) NO EFFECT OF AGENCY ON DUTY OR LIABILITY
8 OF PRINCIPAL.—An agreement or relationship between a
9 trustee and an agent or contractor does not relieve a
10 health information trustee of any duty or liability under
11 this Act.

12 **SEC. 202. AUTHORIZATIONS FOR DISCLOSURE OF PRO-**
13 **TECTED HEALTH INFORMATION FOR TREAT-**
14 **MENT OR PAYMENT.**

15 (a) WRITTEN AUTHORIZATIONS.—A health informa-
16 tion trustee may disclose protected health information for
17 purposes of treatment or payment pursuant to an author-
18 ization executed by an individual who is the subject of the
19 information (or a person acting for the individual pursu-
20 ant to State law) if each of the following requirements is
21 met:

22 (1) WRITING.—The authorization is in written
23 or electronic form, signed or electronically authenti-
24 cated by the individual, and dated.

1 (2) SEPARATE FORMS.—Separate forms author-
2 izing disclosures for treatment and separate forms
3 authorizing disclosures for payment processes are
4 provided to the individual.

5 (3) INFORMATION DESCRIBED.—The informa-
6 tion to be disclosed is specified, or is described, in
7 the authorization.

8 (4) TRUSTEE DESCRIBED.—The trustee who is
9 authorized to disclose such information is specifically
10 identified, or is described, in the authorization.

11 (5) RECIPIENT DESCRIBED.—The person to
12 whom the information is to be disclosed is specifi-
13 cally identified, or is described, in the authorization.

14 (6) RIGHT TO REVOKE OR AMEND.—The au-
15 thorization contains an acknowledgement that the
16 individual who is executing the authorization has the
17 right to revoke or amend the authorization, subject
18 to subsection (b).

19 (7) PURPOSE DESCRIBED.—The authorization
20 describes in detail the purpose for which the infor-
21 mation will be used.

22 (8) STATEMENT OF INTENDED DISCLOSURES.—
23 The authorization contains an acknowledgment that
24 the individual who is executing the authorization has
25 read a statement of any disclosures of the protected

1 health information that the recipient intends to
2 make.

3 (9) USE AND DISCLOSURE RESTRICTED.—The
4 authorization includes a statement that the informa-
5 tion will be used and disclosed solely for one or more
6 purposes specified in the authorization.

7 (10) EXPIRATION DATE SPECIFIED.—The au-
8 thorization specifies a date on which, or event upon
9 which, the authorization expires, which shall be no
10 later than one year after the date on which the au-
11 thorization is executed.

12 (b) REVOCATION OR AMENDMENT OF AUTHORIZA-
13 TION.—

14 (1) IN GENERAL.—An authorization under sub-
15 section (a) shall be subject to revocation and amend-
16 ment at any time by the individual who executed the
17 authorization, except that—

18 (A) the revocation or amendment shall be
19 in writing; and

20 (B) an authorization executed for the pur-
21 pose of validation of expenditures for health
22 care that the individual has authorized to be
23 rendered may not be revoked.

24 (2) NOTICE OF REVOCATION.—A health infor-
25 mation trustee who discloses protected health infor-

1 mation pursuant to an authorization described in
2 subsection (a) that has been revoked shall not be
3 subject to any liability or penalty under this Act if
4 the trustee has no actual or constructive notice of
5 the revocation at the time the trustee makes the dis-
6 closure.

7 (c) MODEL AUTHORIZATIONS.—The Secretary, after
8 providing notice and opportunity for public comment, shall
9 develop and disseminate model written authorizations of
10 the type described in subsection (a) and model statements
11 of intended disclosures of the type described in subsection
12 (a)(7).

13 (d) COPY.—A health information trustee who dis-
14 closes protected health information pursuant to an author-
15 ization under this section shall maintain a copy of the au-
16 thorization for not less than 7 years.

17 **SEC. 203. AUTHORIZATIONS FOR DISCLOSURE OF PRO-**
18 **TECTED HEALTH INFORMATION FOR PUR-**
19 **POSES OTHER THAN TREATMENT OR PAY-**
20 **MENT.**

21 (a) WRITTEN AUTHORIZATIONS.—A health informa-
22 tion trustee may disclose protected health information for
23 a purpose other than treatment or payment pursuant to
24 an authorization executed by an individual who is the sub-
25 ject of the information (or a person acting for the individ-

1 ual pursuant to State law) if each of the following require-
2 ments is met:

3 (1) GENERAL REQUIREMENTS.—The require-
4 ments of paragraphs (1) through (7) of section
5 202(a).

6 (2) STATEMENT OF INTENDED DISCLOSURES.—
7 The statement of intended disclosure shall be in
8 writing, and shall be received by the individual au-
9 thorizing the disclosure on or before the date the au-
10 thorization is executed.

11 (3) EXPIRATION DATE SPECIFIED.—The au-
12 thorization specifies a date on which, or an event
13 upon which, the authorization expires, which shall
14 not occur more than 1 year from the date of the exe-
15 cution of the authorization.

16 (b) LIMITATION ON REQUESTS FOR AUTHORIZA-
17 TIONS.—

18 (1) CONDITION OF TREATMENT OR PAYMENT.—
19 A health information trustee may not condition de-
20 livery of treatment, or payment for services, on the
21 receipt of an authorization described in subsection
22 (a).

23 (2) EMPLOYMENT.—A health information trust-
24 ee may not adversely affect, or condition, the em-
25 ployment of any person based on the agreement or

1 refusal of the person to execute or provide an au-
2 thorization described in subsection (a).

3 (c) REVOCATION OR AMENDMENT OF AUTHORIZA-
4 TION.—

5 (1) IN GENERAL.—An individual may in writing
6 revoke or amend an authorization described in sub-
7 section (a).

8 (2) NOTICE OF REVOCATION.—A health infor-
9 mation trustee who discloses protected health infor-
10 mation pursuant to an authorization described in
11 subsection (a) that has been revoked shall not be
12 subject to any liability or penalty under this Act if
13 the trustee has no actual or constructive notice of
14 the revocation at the time the trustee makes the dis-
15 closure.

16 (d) MODEL AUTHORIZATIONS.—The Secretary, after
17 notice and opportunity for public comment, shall develop
18 and disseminate model written authorizations of the type
19 described in subsection (a) and model statements of the
20 intended disclosures of the type described in subsection
21 (a)(2).

22 **SEC. 204. CREATION OF NONIDENTIFIABLE AND CODED IN-**
23 **FORMATION.**

24 (a) CREATION OF NONIDENTIFIABLE INFORMA-
25 TION.—A health information trustee may disclose pro-

1 tected health information about an individual to an em-
2 ployee, agent, or contractor for the purpose of creating
3 nonidentifiable health information if—

4 (1) the individual is informed of the purpose for
5 the creation of the nonidentifiable information;

6 (2) the individual is given the option to prohibit
7 any specific uses of the nonidentifiable information,
8 such as use of the information for marketing pur-
9 poses; and

10 (3) the health information trustee does not con-
11 dition the delivery of health care, payment for serv-
12 ices, or employment, on the granting by the individ-
13 ual of permission to create the nonidentifiable infor-
14 mation.

15 (b) CREATION OF CODED HEALTH INFORMATION.—

16 A health care provider may create coded health informa-
17 tion, or disclose protected health information about an in-
18 dividual to an employee, agent, or contractor for the pur-
19 pose of creating coded health information, if—

20 (1) the individual is informed of the purpose for
21 the creation of the coded information;

22 (2) the individual is informed of which persons
23 will have the authority to link or match the coded
24 health information to reveal the identity of the indi-
25 vidual;

1 (3) the individual gives written authorization
2 for a disclosure for this purpose in accordance with
3 subsections (a)(1) through (a)(3), (c), and (d) of
4 section 203;

5 (4) the health care provider does not condition
6 the delivery of health care, payment for services, em-
7 ployment, or the terms of employment on the grant-
8 ing by the individual of permission to create the
9 coded health information; and

10 (5) agents and contractors who receive pro-
11 tected health information for the purpose of creating
12 coded health information use the information exclu-
13 sively for such purpose.

14 **SEC. 205. NEXT OF KIN AND DIRECTORY INFORMATION.**

15 (a) NEXT OF KIN.—Except as provided in subsection
16 (c), a health care provider, or a person who receives pro-
17 tected health information under section 206, may disclose
18 protected health information regarding an individual who
19 is an inpatient in a health care facility to the individual's
20 next of kin, to an individual representative of the individ-
21 ual, or to an individual with whom the individual has a
22 significant personal relationship if—

23 (1) the individual who is the subject of the in-
24 formation—

1 (A) has been notified of the individual's
2 right to object at the time of admission to the
3 facility and has not objected to the disclosure;
4 or

5 (B) is in a physical or mental condition
6 such that it would not be possible to notify the
7 individual of the right to object and there are
8 no prior indications that the individual would
9 object; and

10 (2) the information relates to health care cur-
11 rently being provided to the individual at the time
12 of the disclosure.

13 (b) DIRECTORY INFORMATION.—

14 (1) DISCLOSURE.—Except as provided in sub-
15 section (c), a health information trustee may disclose
16 to any person protected health information concern-
17 ing an individual if the information is described in
18 paragraph (2) and the individual who is the subject
19 of the information—

20 (A) has been notified of the individual's
21 right to object and has not objected to the dis-
22 closure; or

23 (B) is in a physical or mental condition
24 such that it would not be possible to notify the
25 individual of the right to object and there are

1 no prior indications that the individual would
2 object.

3 (2) INFORMATION DESCRIBED.—The informa-
4 tion referred to in paragraph (1) is any one or more
5 of the following:

6 (A) The name of the individual who is the
7 subject of the information.

8 (B) The general health status of the indi-
9 vidual, described as critical, poor, fair, stable,
10 or satisfactory, or in terms denoting similar
11 conditions.

12 (C) The location of the individual, if on a
13 premises controlled by a health care provider.

14 (c) EXCEPTION.—A health care provider may not dis-
15 close protected health information without specific author-
16 ization pursuant to section 203—

17 (1) in the case of a disclosure under subsection
18 (b), if disclosure of the location of the individual
19 would reveal specific information about the physical
20 or mental condition of the individual; or

21 (2) in the case of a disclosure under subsection
22 (a) or (b), if the provider has reason to believe that
23 the disclosure could lead to physical, mental, or emo-
24 tional harm to the individual.

25 (d) DECEASED INDIVIDUAL.—

1 (1) IDENTIFICATION.—A health information
2 trustee may disclose protected health information if
3 necessary to assist in the identification of a deceased
4 individual.

5 (2) REGULATIONS.—The Secretary shall de-
6 velop and establish through regulation a procedure
7 for obtaining protected health information relating
8 to a deceased individual when there is no individual
9 representative for such individual.

10 **SEC. 206. EMERGENCY CIRCUMSTANCES.**

11 (a) DISCLOSURE WHEN SUBJECT OF INFORMATION
12 IS IN DANGER.—A health information trustee who receives
13 protected health information under this title may disclose
14 such protected health information to a health care pro-
15 vider or emergency medical personnel, or use such infor-
16 mation in emergency medical circumstances, to the extent
17 necessary to protect the health or safety of an individual
18 who is a subject of such information from serious immi-
19 nent harm.

20 (b) DISCLOSURE WHEN ANOTHER INDIVIDUAL IS IN
21 DANGER.—A health information trustee may disclose pro-
22 tected health information, to the extent necessary, where
23 such trustee determines that—

1 (1) there is an identifiable threat of serious in-
2 jury or death to an identifiable individual or group
3 of individuals; and

4 (2) the disclosure of the information to the per-
5 son is necessary to prevent or significantly reduce
6 the possibility of such threat.

7 **SEC. 207. OVERSIGHT.**

8 (a) IN GENERAL.—A health information trustee,
9 other than a public health authority or a health re-
10 searcher, may disclose protected health information to—

11 (1) a health oversight agency for any function
12 of the agency authorized by law, if—

13 (A) there is probable cause to believe fraud
14 has been committed;

15 (B) the oversight agency is investigating
16 the fraud;

17 (C) the oversight agency has obtained a
18 subpoena for purposes of obtaining the informa-
19 tion; and

20 (D)(i) a subject of the information is be-
21 lieved to have committed the fraud; or

22 (ii) the information is necessary to permit
23 the agency to investigate the fraud; or

24 (2) a health oversight agency charged by law to
25 protect individuals from harm, abuse, neglect, or ex-

1 exploitation, if the information is necessary to inves-
2 tigate whether abuse, neglect, or exploitation of an
3 individual has occurred.

4 (b) USE OF CODED HEALTH INFORMATION.—The
5 health oversight agency shall receive exclusively coded
6 health information under subsection (a) whenever the pur-
7 pose of the agency may be accomplished using only such
8 information.

9 (c) NOTICE TO SUBJECTS.—In any case where an in-
10 dividual who is a subject of protected health information
11 disclosed under subsection (a) is not believed to have com-
12 mitted fraud, the individual shall be notified, at the first
13 practical opportunity—

14 (1) that an investigation described in such sub-
15 section is being conducted;

16 (2) of the reason why disclosure of the informa-
17 tion is necessary; and

18 (3) of all intended subsequent disclosures of the
19 information that the agency intends to make.

20 (d) USE IN ACTION AGAINST INDIVIDUALS.—

21 (1) IN GENERAL.—Subject to paragraph (2),
22 protected health information about an individual
23 that is disclosed under this section may not be used
24 in, or disclosed to any person for use in, an adminis-
25 trative, civil, or criminal action or investigation di-

1 rected against the individual, unless the action or in-
2 vestigation arises out of and is directly related to the
3 purpose for which the disclosure was authorized
4 under subsection (a).

5 (2) SPECIAL RULE.—A health oversight agency
6 may not disclose protected health information re-
7 ceived by the agency under subsection (a)(2) for any
8 purpose other than protecting individuals from
9 harm, abuse, neglect, or exploitation.

10 (e) PUBLIC HEALTH AND HEALTH RESEARCH.—A
11 public health authority may disclose protected health in-
12 formation to a health oversight agency only if such infor-
13 mation is necessary for use in an investigation of whether
14 the authority has committed fraud. A health researcher
15 may disclose protected health information to a health over-
16 sight agency only if such information is necessary for use
17 in an investigation of whether the researcher has commit-
18 ted fraud.

19 **SEC. 208. ACCREDITATION.**

20 (a) IN GENERAL.—A health information trustee may
21 disclose protected health information to an accrediting
22 body for the exclusive purpose of permitting the accredi-
23 ting body to carry out accreditation, licensing, or
24 credentialing activities.

1 (b) USE OF CODED HEALTH INFORMATION.—The
2 accrediting body shall receive exclusively coded health in-
3 formation under subsection (a) whenever the purpose of
4 the body may be accomplished using only such informa-
5 tion.

6 (c) RESTRICTION ON USE AND DISCLOSURE.—A
7 person to whom protected health information is disclosed
8 under subsection (a) may not use or disclose the informa-
9 tion for any purpose other than the purpose for which the
10 information was disclosed to the person.

11 **SEC. 209. PUBLIC HEALTH.**

12 (a) DISCLOSURES BY PROVIDERS.—A health care
13 provider may disclose protected health information about
14 an individual to a public health authority where—

15 (1) the information is disclosed for the purpose
16 of permitting the authority to ascertain the identity
17 of such individual;

18 (2) there is a specific nexus between such indi-
19 vidual's identity and a threat of death or injury to
20 any person; and

21 (3) knowledge of such individual's identity
22 would allow the public health authority to prevent or
23 significantly reduce the possibility of injury or death
24 to any person.

1 (b) LIMITATION ON LIABILITY.—A health informa-
2 tion trustee shall not be liable to any person for a disclo-
3 sure of protected health information under this section
4 that is made based upon a good faith belief by the trustee
5 of a representation made by a public health authority that
6 such disclosure satisfies the requirements of subsection
7 (a).

8 (c) LIMITATION ON USE AND DISCLOSURE BY PUB-
9 LIC HEALTH AUTHORITIES.—A public health authority
10 may not use or disclose protected health information for
11 any purpose other than for public health reporting, sur-
12 veillance, protection, investigation, or intervention.

13 **SEC. 210. HEALTH RESEARCH.**

14 (a) IN GENERAL.—A health information trustee may
15 disclose protected health information, other than coded
16 health information, to a health researcher for use in a re-
17 search project engaged in by the health researcher, if an
18 institutional review board, using standards and procedures
19 that are generally consistent with the official written pol-
20 icy of the Secretary with respect to research involving
21 human subjects conducted, supported, or otherwise subject
22 to regulation by Federal departments and agencies, and
23 this Act, determines that the research project—

24 (1) requires use of the protected health infor-
25 mation for the effectiveness of the project and could

1 not be carried out with either coded or nonidentifi-
2 able health information; and

3 (2) has obtained an authorization for the disclo-
4 sure executed by an individual who is a subject of
5 the information that—

6 (A) is consistent with the requirements of
7 section 203; and

8 (B) in a case where the researcher foresees
9 using or disclosing the information for any pur-
10 pose subsequent to the conclusion of the
11 project, specifically states—

12 (i) such intent; and

13 (ii) that the individual has the right
14 to limit such subsequent uses or disclo-
15 sures consistent with this Act.

16 (b) USE OF CODED OR NONIDENTIFIABLE HEALTH
17 INFORMATION.—A health information trustee may dis-
18 close coded health information that is not contained in a
19 protected health information subfile, or nonidentifiable
20 health information, to a health researcher for use in a re-
21 search project engaged in by the health researcher upon
22 approval of the proposed research by an institutional re-
23 view board, regardless of whether the researcher has ob-
24 tained an authorization for the disclosure consistent with
25 the requirements of section 203.

1 (c) ANONYMIZATION OF PREVIOUSLY STORED BIO-
2 LOGICAL SAMPLES.—The Secretary may develop interim
3 guidelines for the use by a health researcher of biological
4 samples derived from a human body collected before the
5 effective date of this Act. Such guidelines shall address
6 the requirements pertinent to a health researcher who
7 wishes to use stored biological samples derived from a
8 human body in nonidentifiable or coded form. Such guide-
9 lines shall authorize a health researcher, for the purpose
10 of facilitating future health research—

11 (1) to convert protected health information into
12 nonidentifiable information or coded health informa-
13 tion, if such conversion is permitted in a written au-
14 thorization; or

15 (2) if no such authorization exists, to make
16 such conversion after publishing notice of the re-
17 searcher's intent and providing individuals the op-
18 portunity to prohibit the use of their biological sam-
19 ples for such purpose.

20 (d) OBLIGATIONS OF RECIPIENT.—A person who re-
21 ceives protected health information pursuant to subsection
22 (a)—

23 (1) shall remove or destroy, at the earliest op-
24 portunity consistent with the purposes of the project,

1 information that would enable an individual to be
2 identified, unless—

3 (A) an institutional review board has de-
4 termined that there is a health or research jus-
5 tification for retention of such identifiers; and

6 (B) there is an adequate plan to protect
7 the identifiers from disclosure that is inconsis-
8 ent with this section; and

9 (2) shall use the information solely for purposes
10 of the health research project for which disclosure
11 was authorized by an institutional review board
12 under subsection (a).

13 **SEC. 211. JUDICIAL AND ADMINISTRATIVE PURPOSES.**

14 A health care provider, health plan, health oversight
15 agency, employer, school, institution of higher education,
16 insurer, court, or a person who receives protected health
17 information pursuant to section 206 may disclose pro-
18 tected health information about an individual—

19 (1) pursuant to the requirements governing
20 subpoenas, warrants, and court orders under sec-
21 tions 212 and 213, where such information has been
22 determined to be discoverable by a court under any
23 applicable rules of civil or criminal procedure;

1 (2) to a court, and to others as ordered by the
2 court, if the information is developed in response to
3 a court-ordered physical or mental examination;

4 (3) where the subject of such information has
5 brought a claim for medical malpractice against a
6 health care provider and the information is nec-
7 essary for the defense of the claim; and

8 (4) to legal counsel for the person making the
9 disclosure, where the disclosure is necessary to en-
10 sure compliance with this Act or any other legal re-
11 quirement.

12 **SEC. 212. GENERAL REQUIREMENTS GOVERNING SUBPOE-**
13 **NAS.**

14 (a) IN GENERAL.—A health care provider, health
15 plan, health oversight agency, employer, school, institution
16 of higher education, insurer, court, or a person who re-
17 ceives protected health information pursuant to section
18 206 may disclose protected health information to any per-
19 son, other than a law enforcement authority, under section
20 211(1), if the disclosure is pursuant to a subpoena issued
21 on behalf of a party to a lawsuit or other judicial or ad-
22 ministrative proceeding who has complied with subsection
23 (b) or (c), and subsection (d).

24 (b) REQUEST FOR ACCESS BY COUNSEL TO REVIEW
25 PROTECTED HEALTH INFORMATION.—A person may have

1 access to protected health information under subsection
2 (a), by means solely of a review of the information by the
3 person's counsel, acting in the capacity of an officer of
4 the court, and on premises of, and under the control of,
5 the court, if—

6 (1) the person has included in a subpoena a
7 proffer of evidence specifying with reasonable speci-
8 ficity the information to which access is sought and
9 the precise grounds for seeking such access for re-
10 view;

11 (2) a copy of such subpoena for access to re-
12 view, together with a notice of the individual's right
13 to challenge the subpoena under subsection (d), has
14 been served upon the individual on or before the
15 date of return of the subpoena;

16 (3)(A) 15 days have passed since the date of
17 service on the individual, and within that period the
18 individual has not initiated a challenge in accordance
19 with subsection (d)(1); or

20 (B) such access is ordered by the court; and

21 (4) such counsel agrees not to copy such infor-
22 mation, remove such information from the court
23 premises, or disclose the information to any person
24 other than the person permitted access under this
25 subsection.

1 (c) REQUEST TO OBTAIN PROTECTED HEALTH IN-
2 FORMATION FOR INTRODUCTION IN COURT.—

3 (1) REQUIREMENTS FOR OBTAINING INFORMA-
4 TION.—A person may obtain protected health infor-
5 mation about an individual pursuant to a subpoena,
6 for purposes of introducing such information as evi-
7 dence in a court, only if—

8 (A) counsel for the person has obtained ac-
9 cess to the information under subsection (b);

10 (B) a copy of the subpoena to obtain the
11 information for introduction in court, specifying
12 the precise information sought and the precise
13 grounds for seeking introduction of the infor-
14 mation as evidence in court, together with a no-
15 tice of the individual's right to challenge the
16 subpoena under subsection (d), has been served
17 upon the individual on or before the date of re-
18 turn of such subpoena; and

19 (C)(i) 15 days have passed since the date
20 of service on the individual, and within that
21 time period the individual has not indicated a
22 challenge in accordance with subsection (d)(1);
23 or

24 (ii) the information is ordered to be pro-
25 vided to the court.

1 (2) USE AND DISCLOSURE.—A person who ob-
2 tains protected health information under paragraph
3 (1) may use and disclose such information only for
4 the purpose of prosecuting or defending the lawsuit
5 or other judicial or administrative proceeding de-
6 scribed in subsection (a).

7 (d) CHALLENGE PROCEDURES.—

8 (1) MOTION TO QUASH SUBPOENA.—After
9 being served of a copy of a subpoena seeking access
10 for review by counsel of, or access to, protected
11 health information under subsection (b), or a sub-
12 poena seeking to obtain protected health information
13 for introduction as evidence in court, under sub-
14 section (c), an individual who is a subject of such in-
15 formation may file in any court of competent juris-
16 diction a motion to quash the subpoena.

17 (2) STANDARD FOR DECISION.—

18 (A) IN GENERAL.—The court shall grant a
19 motion under paragraph (1) unless the respond-
20 ent demonstrates—

21 (i) by clear and convincing evidence
22 that the information is necessary in rela-
23 tion to the lawsuit or other judicial or ad-
24 ministrative proceeding with respect to

1 which the information is sought, includ-
2 ing—

3 (I) a demonstration that use or
4 disclosure of solely nonidentifiable
5 health information would be insuffi-
6 cient to accomplish the purpose for
7 which the information is sought; and

8 (II) if protected health informa-
9 tion that is not coded health informa-
10 tion is sought, a demonstration that
11 use or disclosure of coded health in-
12 formation would be insufficient to ac-
13 complish the purpose for which the in-
14 formation is sought; and

15 (ii) that the need of the respondent
16 for the information outweighs the privacy
17 interest of the individual.

18 (B) CRITERIA FOR DECISION.—In deter-
19 mining whether the need of the respondent for
20 the information outweighs the privacy interest
21 of the individual, the court shall consider—

22 (i) the particular purpose for which
23 the information was collected;

24 (ii) the invasion of the individual's
25 privacy caused by the disclosure;

1 (iii) the degree to which disclosure of
2 the information would embarrass, injure,
3 or further invade, the privacy of the indi-
4 vidual;

5 (iv) the effect of the disclosure on the
6 individual's future health care;

7 (v) the importance of the information
8 to the lawsuit or proceeding; and

9 (vi) any other relevant factor.

10 (3) ATTORNEY'S FEES.—In the case of a mo-
11 tion brought under paragraph (1) in which the indi-
12 vidual who brought the motion has prevailed in
13 whole or in part, the court may assess against the
14 respondent a reasonable attorney's fee and other liti-
15 gation costs and expenses (including expert fees)
16 reasonably incurred.

17 (e) SEALING OF INFORMATION.—Any portion of a
18 record of a court that contains protected health informa-
19 tion disclosed under this section shall be kept by the court
20 under seal and used or disclosed only pursuant to an order
21 of the court consistent with this section.

22 **SEC. 213. ADDITIONAL REQUIREMENTS FOR LAW ENFORCE-**
23 **MENT ACCESS.**

24 (a) LAW ENFORCEMENT SUBPOENAS AND WAR-
25 RANTS IN GENERAL.—A health care provider, health plan,

1 health oversight agency, employer, school, institution of
2 higher education, insurer, court, or a person who receives
3 protected health information pursuant to section 206 may
4 disclose protected health information to a law enforcement
5 authority under section 211(1), if—

6 (1)(A) the disclosure is made pursuant to a
7 subpoena for review under section 212(b), a sub-
8 poena for purposes of introducing evidence in a
9 court under section 212(c), or both, issued under the
10 authority of a grand jury or a court; and

11 (B) the requirements of subsections (b) through
12 (e) of section 212, and subsections (b) and (c) of
13 this section, are satisfied;

14 (2) the disclosure is made pursuant to a judicial
15 warrant for search and seizure and the requirements
16 of subsection (d) are satisfied; or

17 (3)(A) the disclosure is made pursuant to a
18 subpoena for purposes of introducing evidence in a
19 court under section 212(c), issued under the author-
20 ity of a grand jury or a court, and obtained pursu-
21 ant to subsection (d)(5) following the execution of a
22 judicial warrant for search and seizure under sub-
23 section (d); and

24 (B) the requirements of subsections (c) through
25 (e) (other than subsection (c)(1)(A)) of section 212,

1 and subsections (b) and (c) of this section, are satis-
2 fied.

3 (b) CLEAR AND CONVINCING REQUIREMENT.—A law
4 enforcement authority may not obtain protected health in-
5 formation about an individual under subsection (a) unless
6 the authority demonstrates by clear and convincing evi-
7 dence that the information is necessary to a legitimate law
8 enforcement inquiry into a particular violation of criminal
9 law being conducted by the authority.

10 (c) LIMITATION ON USE AND DISCLOSURE FOR
11 OTHER LAW ENFORCEMENT INQUIRIES.—Protected
12 health information about an individual that is disclosed
13 under this section may not be used in, or disclosed to any
14 person for use in, any administrative, civil, or criminal ac-
15 tion or investigation directed against the individual, unless
16 the action or investigation arises out of, or is directly re-
17 lated to, the law enforcement inquiry for which the infor-
18 mation was obtained.

19 (d) REQUIREMENTS FOR WARRANTS FOR SEARCH
20 AND SEIZURE.—

21 (1) LIMITED PURPOSE.—A health care pro-
22 vider, health plan, health oversight agency, em-
23 ployer, school, institution of higher education, in-
24 surer, or a person who receives protected health in-
25 formation pursuant to section 206 may disclose pro-

1 tected health information to a law enforcement au-
2 thority pursuant to a warrant for search and sei-
3 zure, issued under the authority of a court, for the
4 exclusive purpose of permitting the authority to se-
5 cure the information described in the warrant for de-
6 livery to the court.

7 (2) LIMITATION ON EXECUTION OF WAR-
8 RANTS.—In executing a warrant under paragraph
9 (1), a law enforcement authority shall engage in the
10 most minimal examination of protected health infor-
11 mation that is necessary in order to determine
12 whether the information is or is not within the scope
13 of the warrant. The authority immediately shall
14 place any such information that the authority deter-
15 mines is within the scope of the warrant under seal,
16 and shall deliver such sealed information, without
17 any further examination or other use or disclosure,
18 to the court. The authority may not use or disclose
19 for any purpose protected health information that
20 the authority determines is not within the scope of
21 the warrant, but that is obtained or discovered by
22 the authority directly or indirectly through execution
23 of the warrant.

24 (3) NOTICE OF WARRANT.—A law enforcement
25 authority that obtains protected health information

1 about an individual pursuant to the execution of a
2 warrant under paragraph (2) shall, not later than
3 30 days after the date of such execution, serve the
4 individual with, or mail to the last known address
5 of the individual, a notice that protected health in-
6 formation about the individual was obtained, to-
7 gether with a notice of the individual's right to chal-
8 lenge the warrant under paragraph (4).

9 (4) CHALLENGE PROCEDURES FOR WAR-
10 RANTS.—

11 (A) MOTION TO QUASH.—Within 15 days
12 after the date of service of a notice of execution
13 of a warrant of a law enforcement authority
14 seeking protected health information about an
15 individual under paragraph (3), the individual
16 (or any other person who was in possession of
17 the information and against whom the warrant
18 was executed) may file in any court of com-
19 petent jurisdiction a motion to quash the war-
20 rant.

21 (B) STANDARD FOR DECISION.—The court
22 shall grant a motion under subparagraph (A)
23 unless the law enforcement authority dem-
24 onstrates by clear and convincing evidence that
25 the protected health information is necessary to

1 a legitimate law enforcement inquiry being con-
2 ducted by the law enforcement authority and
3 the government authority's need for the infor-
4 mation outweighs the privacy interest of the in-
5 dividual.

6 (C) ATTORNEY'S FEES.—In the case of a
7 motion brought under subparagraph (A) in
8 which the individual has prevailed, in whole or
9 in part, the court may assess against the law
10 enforcement authority reasonable attorney's
11 fees and other litigation costs (including expert
12 fees) reasonably incurred.

13 (5) ACTION IN COURT ON INFORMATION DELIV-
14 ERED.—Upon termination of the period described in
15 paragraph (4)(A) (in a case where a motion to
16 quash is not filed under such paragraph), or upon
17 the denial of a motion to quash under such para-
18 graph, the law enforcement authority may obtain
19 protected health information delivered to the court
20 under this subsection solely through a disclosure
21 under subsection (a)(3).

22 (6) SEALING OF INFORMATION.—Any protected
23 health information that is delivered to a court under
24 this section shall be kept by the court under seal and

1 used or disclosed only pursuant to an order of the
2 court consistent with this section.

3 **TITLE III—SANCTIONS**

4 **Subtitle A—Civil Sanctions**

5 **SEC. 301. CIVIL PENALTY.**

6 (a) VIOLATION.—Any person who the Secretary de-
7 termines has materially failed to comply with this Act shall
8 be subject, in addition to any other penalties that may
9 be prescribed by law, to—

10 (1) a civil penalty of not more than \$25,000 for
11 each such violation, but not to exceed \$150,000 in
12 the aggregate for multiple violations in any one year;
13 and

14 (2) a civil penalty of not more than \$500,000
15 and exclusion from participation in the program
16 under title XVIII of the Social Security Act, the pro-
17 gram under title XIX of such Act, and any other
18 federally funded health care program, if the Sec-
19 retary finds that such violations have occurred with
20 such frequency as to constitute a general business
21 practice.

22 (b) PROCEDURES FOR IMPOSITION OF PENALTIES.—
23 Section 1128A of the Social Security Act, other than sub-
24 sections (a) and (b) and the second sentence of subsection
25 (f) of that section, shall apply to the imposition of a civil,

1 monetary, or exclusionary penalty under this section in the
2 same manner as such provisions apply with respect to the
3 imposition of a penalty under section 1128A of such Act.

4 **SEC. 302. CIVIL ACTION.**

5 (a) IN GENERAL.—An individual who is aggrieved by
6 conduct in violation of this Act may bring a civil action
7 to recover—

8 (1) such preliminary and equitable relief as the
9 court determines to be appropriate;

10 (2) the greater of—

11 (A) actual damages; and

12 (B) liquidated damages of—

13 (i) \$25,000, in the case of a material
14 violation; or

15 (ii) \$50,000, in the case of a violation
16 that was willful or resulted in profit or
17 monetary gain; and

18 (3) punitive damages.

19 (b) ATTORNEY'S FEES.—In the case of a civil action
20 brought under subsection (a) in which the individual has
21 substantially prevailed, the court may assess against the
22 respondent a reasonable attorney's fee and other litigation
23 costs and expenses (including expert fees) reasonably in-
24 curred.

1 (c) LIMITATION.—No action may be commenced
2 under this section by an individual more than 3 years after
3 the date on which the violation was or should reasonably
4 have been discovered by the individual.

5 **Subtitle B—Criminal Sanctions**

6 **SEC. 311. WRONGFUL DISCLOSURE OF PROTECTED** 7 **HEALTH INFORMATION.**

8 (a) OFFENSE.—Whoever knowingly—

9 (1) obtains protected health information relat-
10 ing to an individual in violation of this Act;

11 (2) discloses protected health information to an-
12 other person in violation of this Act;

13 (3) coerces or attempts to coerce a health infor-
14 mation trustee to disclose protected health informa-
15 tion in violation of this title; or

16 (4) without authorization pursuant to this Act,
17 identifies or attempts to identify an individual who
18 is the subject of protected health information that a
19 health information trustee has converted into coded
20 health information,

21 shall be punished as provided in subsection (b).

22 (b) PENALTIES.—A person referred to in subsection

23 (a) shall be fined under title 18, United States Code, im-
24 prisoned not more than 1 year, or both, except that—

1 (1) if the offense is committed under false pre-
2 tenses, the person shall be fined under title 18,
3 United States Code, imprisoned not more than 5
4 years, or excluded from participation in the program
5 under title XVIII of the Social Security Act, the pro-
6 gram under title XIX of such Act, or any other fed-
7 erally funded health care program, or any combina-
8 tion of such penalties; and

9 (2) if the offense is committed with intent to
10 sell, transfer, or use protected health information for
11 commercial advantage, personal gain, or malicious
12 harm, the person shall be fined under title 18, Unit-
13 ed States Code, or imprisoned not more than 10
14 years, or excluded from participation in the program
15 under title XVIII of the Social Security Act, the pro-
16 gram under title XIX of such Act, or any other fed-
17 erally funded health care program, or any combina-
18 tion of such penalties.

19 **TITLE IV—MISCELLANEOUS**

20 **SEC. 401. REGULATIONS.**

21 (a) PROMULGATION.—

22 (1) CONSULTATION WITH ADVISORY GROUP.—
23 In promulgating regulations under this Act, the Sec-
24 retary shall appoint and consult an advisory group
25 of knowledgeable individuals.

1 (2) MEMBERSHIP.—The advisory group shall
2 consist of at least 7 but no more than 12 individ-
3 uals, including representatives of—

- 4 (A) health care providers;
- 5 (B) health care consumers;
- 6 (C) health plans;
- 7 (D) privacy advocates; and
- 8 (E) electronic security experts.

9 (3) RESPONSIBILITIES.—The advisory group
10 shall review all proposed rules and regulations and
11 submit recommendations to the Secretary. The advi-
12 sory group shall also assist the Secretary in estab-
13 lishing the standards for compliance with rules and
14 regulations, in developing an annual report to the
15 Congress on the status of the requirements set forth
16 in this Act, their cost impact, and any recommenda-
17 tions for modifications to this Act in order to ensure
18 efficient and confidential electronic interchange of
19 protected health information.

20 (b) CONSULTATION WITH OTHERS.—In promulgat-
21 ing regulations under this Act, the Secretary may con-
22 sult—

- 23 (1) privacy, industry, health care professional,
24 and consumer groups;
- 25 (2) medical societies; and

1 (3) academic computer security and privacy ex-
2 perts.

3 **SEC. 402. RELATIONSHIP TO OTHER LAWS.**

4 (a) IN GENERAL.—Nothing in this Act shall be con-
5 strued to preempt any provision of State law or any privi-
6 lege, whether derived from statute or common law, that—

7 (1) more completely protects the confidentiality
8 or privacy of an individual with respect to protected
9 health information about the individual than does
10 this Act; or

11 (2) provides a greater right of access to pro-
12 tected health information to a subject of the infor-
13 mation than does this Act.

14 (b) CRIMINAL PENALTIES.—A State may establish
15 and enforce criminal penalties with respect to a failure to
16 comply with a provision of this Act.

17 (c) PRIVILEGES.—This Act does not preempt or mod-
18 ify State common or statutory law to the extent such law
19 concerns a privilege of a witness or person in a court of
20 the State. This Act does not supersede or modify Federal
21 common or statutory law to the extent such law concerns
22 a privilege of a witness or person in a court of the United
23 States and more completely protects the confidentiality or
24 privacy of an individual with respect to protected health
25 information about the individual than does this Act. The

1 execution of an authorization pursuant to section 202 or
2 203 may not be construed as a waiver of any such privi-
3 lege.

4 (d) CERTAIN DUTIES UNDER STATE OR FEDERAL
5 LAW.—This Act does not preempt, supersede, or modify
6 the operation of any of the following:

7 (1) Any law that provides for the reporting of
8 vital statistics such as birth or death information.

9 (2) Any law requiring the reporting of abuse or
10 neglect information about any individual.

11 (3) Any State law relating to public or mental
12 health that prevents or otherwise restricts disclosure
13 of protected health information otherwise permitted
14 under this Act.

15 (4) Subpart II of part E of title XXVI of the
16 Public Health Service Act (relating to notifications
17 of emergency response employees of possible expo-
18 sure to infectious diseases).

19 (5) Any Federal law or regulation governing
20 confidentiality of alcohol and drug patient records.

21 (6) The Americans With Disabilities Act of
22 1990.

23 (7) Any Federal or State statute that estab-
24 lishes a privilege for records used in health profes-
25 sional peer review activities.

1 **SEC. 403. EFFECTIVE DATES.**

2 (a) IN GENERAL.—Except as provided in subsection
3 (b), this Act shall take effect on the date that is 18 months
4 after the date of the enactment of this Act.

5 (b) PROVISIONS EFFECTIVE IMMEDIATELY.—A pro-
6 vision of this Act shall take effect on the date of the enact-
7 ment of this Act if the provision imposes on the Secretary
8 a duty to develop, establish, or promulgate regulations,
9 guidelines, or model forms.

10 (c) DEADLINE FOR REGULATIONS.—The Secretary
11 shall promulgate regulations implementing this Act not
12 later than the date that is 12 months after the date of
13 the enactment of this Act.

14 **SEC. 404. APPLICABILITY.**

15 (a) PROTECTED HEALTH INFORMATION.—Except as
16 provided in subsection (b), the provisions of this Act shall
17 apply to any protected health information that is received,
18 created, used, maintained, or disclosed by a health infor-
19 mation trustee on or after the date that is 18 months after
20 the date of the enactment of this Act, regardless of wheth-
21 er the information existed or was disclosed prior to such
22 date.

23 (b) AUTHORIZATIONS FOR DISCLOSURES.—An au-
24 thorization for the disclosure of protected health informa-
25 tion about a protected individual that is executed by the
26 individual before the date that is 18 months after the date

1 of the enactment of this Act, and is recognized and valid
2 under State law on the day before such date, shall remain
3 valid and shall not be subject to the requirements of title
4 II until the date that is 30 months after the date of the
5 enactment of this Act, or the occurrence of the date or
6 event in the authorization upon which the authorization
7 expires, whichever occurs earlier.

